Orascoptic DK™

User Manual

Orascoptic

A KERR COMPANY

Orascoptic DK is a versatile, 3-in-1 dental device that employs a handheld LED light source and three unique, interchangeable diagnostic instruments.

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1. Orascoptic DK Kit Components

Each DK kit contains the following components:

- Six 30 ml bottles of Orascoptic/DL Rinse (1% Acetic Acid Solution)
- LED Light Source (batteries included)
- Oral Lesion Screening Instrument
- Transillumination Instrument
- Lighted Mirror Instrument

2. The LED Light Source

The LED light source is the black aluminum hand piece that contains a high-intensity LED light source and is powered by three 1.5 Volt N type batteries (included).

Indications for Use

The LED light source emits light through any one of the three diagnostic instruments that comprise the Orascoptic DK kit. Each instrument is designed to improve visualization within the oral cavity for specific applications described later in this manual.

Light Source Operation And First Time Use

Remove the white strip isolating the batteries by turning the end cap at the bottom of the aluminum barrel counter clockwise. When replacing the end cap, be sure the cap is straight and then rotate clockwise.

There are two ways to emit light from the source:

1. For intermittent light, depress the black button on the end cap.
2. For continuous light, turn the end cap clockwise until the light comes on. Turn the light off by rotating the end cap slightly counter-clockwise.

If the Orascoptic DK is to be placed back into the original box, be sure the end cap is rotated sufficiently counter clockwise so that the light does not come on.

Attaching The Diagnostic Instruments

Each of the three Orascoptic DK diagnostic instruments can be inserted into the plastic chuck at the top of the aluminum barrel. Insert an instrument into the plastic chuck with firm pressure. The stainless steel ferrule at the end of the instrument should be covered by the plastic chuck and a slight click may be heard. To remove, rotate slightly and pull on the instrument at the same time.

WARNING: THE INSTRUMENTS ARE FRAGILE – HANDLE WITH CARE.

3. Oral Lesion Screening Instrument

Device Description

Powered by the LED light source, the oral lesion screening instrument emits a diffused blue white light to be used for the examination of the oral mucosa.

Indications For Use

This device is used as an aid to improve the visualization of oral lesions. It is designed to be used by a dentist, hygienist, or health care provider, in combination with a traditional examination by incandescent light.

Theory of Operation

By having the patient rinse with a mild acetic acid solution, the refractile properties of intra-oral tissue are changed. When this tissue is illuminated by the diffused light from the special Orascoptic DK instrument, acetowhite or leukoplakic lesions become more visible.

Instructions For Performing Orascoptic DK Oral Lesion Screening Exam

1. A conventional examination of the oral cavity should be performed. The dental professional should carefully document the presence of any acetowhite lesions in any of the following locations:
   - dorsal, lateral and ventral tongue
   - floor of the mouth
   - attached gingiva
   - buccal mucosa
   - hard and soft palate

2. The patient should now rinse their mouth with Orascoptic DK rinse (1% acetic acid solution) for 60 seconds and then expectorate.

3. Turn off overhead light. The room need not be in complete darkness, but rather should now be dimly lit.

4. Repeat the exam using illumination from the Orascoptic DK oral lesion screening instrument. Look for acetowhite lesions – document location of lesions as mentioned in number 1 above.

5. Next, have the patient rinse with water and expectorate. Most Orascoptic DK exams can be completed in less than three minutes – without discomfort or inconvenience to your patients.

6. Take appropriate action by either:
   - Documenting absence of acetowhite lesions.
   - Advise patient that lesions should be watched closely and schedule a follow-up appointment within a two week period.
   - Refer patient to an oral surgeon for possible biopsy.

7. Document results of the examination.

Contradications
The Orascoptic DK oral lesion screening exam should never be used without prior conventional oral examination with incandescent light.

Warnings/Precautions
1. The Orascoptic DK is to be used in addition to a conventional oral examination. Orascoptic DK is intended to visualize acetowhite lesions, but not intended to rank or diagnose such lesions.
2. Orascoptic DK rinse is not intended to be swallowed. It is harmless if it is accidentally ingested.
3. For oral use only. Keep out of reach of children.
4. Store Orascoptic DK rinse in a cool dry place.

Adverse Effects
None have been identified.

4. Transillumination Instrument

Device Description
Powered by the LED light source, the transillumination instrument emits a focused beam of light to help visualize crown fractures and caries in teeth.

Transillumination is the technique of viewing fractures and caries by passing an intense light through them. Transillumination is based on the fact that a healthy tooth structure will transmit greater light than a fracture or cary.

Instructions for Use
To help visualize anterior caries, place the probe on the labio-cervical region of the tooth and examine from the lingual with a mouth mirror.

To help visualize posterior proximal caries, place the probe on the bucco-cervical area of the tooth. Light passes into the cervical region and then radiates occlusally. Caries may appear as a dark triangular or rectangular shadow on the occlusal.

5. Lighted Mirror Instrument

Device Description

Powered by the LED light source, the mirror provides additional light for hard to reach places within the oral cavity.

6. Cleaning and Maintenance

Cleaning – Light Source

The aluminum light source barrel can be wiped down with most any disinfectant. Do not spray disinfectant directly onto the unit. **Be especially careful not to get disinfectant into the top of the barrel, since this could damage the LED light source or reduce the light output.** ***DO NOT AUTOCLAVE.***

Cleaning – Oral Lesion Screening, Transillumination, and Lighted Mirror Instruments

All of the instrument attachments can be wiped with disinfectant, cold sterilized, autoclaved, or heat sterilized. It is not recommended they be chemclaved.

Maintenance

The LED light source has a useful life of 30,000 hours.

The batteries have a useful life of approximately 20-30 hours. If the device is not going to be used for more than six months, it is recommended that the batteries be removed.

When replacing batteries, it is important that they be placed in proper polarity. Place each battery with the positive (+) terminal in front, towards the LED.

7. Replacement Parts and Accessories:

AD-ORDK-LEDHANDLE	LED Light Source (batteries included)
AD-ORDK-TRANSILLUM	Transilluminator Attachment
AD-ORDK-MIRROR	Mirror Attachment
AD-ORDK-LIGHTWAND	Oral Lesion Screening Attachment
AD-ORDK-BATTERY	Batteries (Set of 3)
AD-ORDK-RINSE-12PK	DK Rinse - 12 bottles
AD-ORDK-RINSE-24PK	DK Rinse - 24 bottles
AD-ORDK-SLEEVE	Protective Plastic Sleeve (Box of 250)

8. Warranty

Kerr Corporation provides a 1-year limited warranty on all components and features of the Orascoptic DK product.

Under this warranty, Kerr Corporation warrants that the LED light source, cancer screening instrument, transillumination instrument, and lighted mirror instrument, when new, and for the time period specified, will be free of defects in material and workmanship, and perform in accordance with manufacturer's specifications, when subject to normal use and service from Kerr Corporation or its authorized agent for the time period of the warranty. The warranty period begins on the original date of purchase from Kerr Corporation.

The warranty, defined as "limited," does not cover breakage or failure due to tampering, misuse, neglect, accidents, improper installation, modification, shipping, or improper maintenance, service or cleaning procedures. The warranty does not cover failure of the batteries. The warranty is also void if the Orascoptic DK product is not used in accordance with manufacturer's recommendations or instructions, or if serviced by other than Kerr Corporation or its authorized agent.

Kerr Corporation will replace any component of the Orascoptic DK kit found to be defective with a new product, FOB at the Kerr Corporation facility in Middleton, Wisconsin, USA. It shall be the purchaser's responsibility to return the product, in appropriate packing materials, so as to prevent accidental breakage in transit, and sufficiently cleaned and disinfected, directly to Kerr Corporation. Kerr Corporation reserves the right, at its sole discretion, to refuse to replace the product if the product is deemed to be unsanitary. It will be the responsibility of the purchaser to arrange for the product to be returned to the purchaser for appropriate cleaning and sanitation, and the purchaser shall be responsible for all shipping charges.

In no event shall Kerr Corporation's liability be greater than the original purchase price of the product. Nor shall Kerr Corporation be held liable for consequential or special damages, or for transportation, installation, adjustment or other expenses, which may arise in connection with such products or parts. This product warranty applies only to customers in the United States of America (USA), Canada or to units sold to and by authorized and approved international dealers. This warranty is non-transferable and shall only apply to the original purchaser of the product, as exclusively contained in Kerr Corporation's records. THIS WARRANTIY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER STATEMENTS, WARRANTIES OR GUARANTEES, EXPRESS OR IMPLIED, BY KERR CORPORATION OR ITS AUTHORIZED REPRESENTATIVE, INCLUDING WARRANTIES WITH RESPECT TO DESCRIPTION, QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The limits

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